

**Notice of Allowability**

Application No.

09/761,466

Examiner

Celine X Qian

Applicant(s)

LEE ET AL.

Art Unit

1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the communication filed on 9/24/03.
2. ☒ The allowed claim(s) is/are 1-6, 8, 9, 11, 12, 18 and 19.
3. ☒ The drawings filed on 24 September 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
(a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.  
(b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.  
(c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                           |                                                                            |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>1202</u> | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material    | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|                                                                                                           | 9 <input type="checkbox"/> Other                                           |

*Anne-Marie Falk*  
**ANNE-MARIE FALK, PH.D**  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 8/21/03, Applicants requested an extension of time and authorized the Director to charge Deposit Account No. 03-2095 the required fee for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative Kristina Brady on 8/21/03.

The application has been amended as follows:

Claim 1. A substantially purified nucleic acid molecule comprising an enhancer element having:

(a) a segment with at least 95% sequence identity to the sequence of SEQ ID NO:1 and a segment with at least 95% sequence identity to the sequence of SEQ ID NO:2;

(b) at least 95% sequence identity to the sequence of SEQ ID NO:3; or

(c) at least 95% sequence identity to SEQ ID NO:4.

Claim 4. The nucleic acid molecule of claim 1, wherein said enhancer element [nucleic acid molecule] comprises a binding site selected from the group consisting of Mef2, dHAND, GATA, TGF- $\beta$ , CarG, E-box, and CsX/Nkx2.5 binding sites.

Claim 5. The nucleic acid molecule of claim 4, wherein said enhancer element [nucleic acid molecule] further comprises an Sp-1 binding site.

Claim <sup>10</sup>~~12~~. An expression vector comprising a gene linked to a regulatory sequence wherein said sequence is a cardiac enhancer element comprising:

(a) a segment with at least 95% sequence identity to the sequence of SEQ ID NO:1 and a segment with at least 95% sequence identity to the sequence of SEQ ID NO:2;

(b) at least 95% sequence identity to the sequence of SEQ ID NO:3; or

(c) at least 95% sequence identity to SEQ ID NO:4.

Claim 20. cancelled.

As requested by Applicants, the following is a clarification of the term “enhancer element.” It is understood by Applicants and the examiner that the “enhancer element” encompasses both A1 region and A2 region, and all the binding sites located either within these two regions or between the two regions. Applicants authorized the amendment of claims 4 and 5 based on this understanding.

### ***Conclusion***

This application is in condition for allowance except for the following formal matters:

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as

acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Celine Qian, Ph.D.